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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,727

06/25/2003

Craig A. Rosen

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HUMAN GENOME SCIENCES INC.  
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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

04/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,727	<b>Applicant(s)</b> ROSEN ET AL.	
	<b>Examiner</b> Patricia A. Duffy	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-37,41-46,51,52,55-67,69,70,79-86 and 97-104 is/are pending in the application.
- 4a) Of the above claim(s) 22-32,57-66,79-86 and 97-104 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,7-14,17-21,33-37,41-46,51,52,55,67,69 and 70 is/are allowed.
- 6) ☒ Claim(s) 5,6,15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **RESPONSE TO AMENDMENT**

The amendment filed 1-22-08 has been entered into the record. Claims 2-4, 38-40, 47-50, 53-54, 68, 71-78 and 87-96 have been cancelled. Claims 1, 5-37, 41-46, 51, 52, 55-67, 69, 70, 79-86, 97-104 are pending. Claims 1, 5-21, 33-46, 51, 52, 55, 67, 69 and 70 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

### ***Election/Restrictions***

This application contains claims 22-32, 57-66, 79-86, and 97-104 are drawn to an invention nonelected with traverse in the response filed 7-6-07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The request for rejoinder is again noted but all the product claims are not in condition for allowance.

### ***Rejections Withdrawn***

The objection to the specification with regard to the peptide sequence "RKKR" at page 177 [0347] as lacking an appropriate sequence identifier is withdrawn in view of Applicants amendments to the specification.

The rejection of claims 69 and 70 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the deposit assurance provided by Applicants.

### ***Rejections Maintained***

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The use of trademarks at pages 147, 150 and 153 have been noted in this application. It should be capitalized wherever it appears *and be accompanied by the generic terminology*.

Applicants query this objection because the trademarks have been capitalized. This is insufficient; the requirement is that trademarks "*be accompanied by the generic terminology*". In the instant case, the trademarks are not accompanied by the generic terminology.

Claims 5, 6, 15 and 16 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody or fragment thereof that binds protective antigen 83 (PA83) of *Bacillus anthracis* comprising the heavy chain complementary determining regions: CDR1, CDR2, CDR3 as set forth in Table 1 (SEQ ID NO:53) and the light chain complementary determining regions: CDR 1, CDR2 and CDR3 as set forth in Table 1 (SEQ ID NO:53), wherein said antibody inhibits the binding of PA 83 to the anthrax receptor (ATR) or capillary morphogenesis protein 2, protease cleavage of PA into PA 20 and PA63 and pore formation and antibodies having a  $K_d$  less than or equal to  $10^{-10}$  M, it does not reasonably provide enablement for changes to the CDR's or random combinations of CDR's from heavy and light chain variable regions and *does not provide enablement for antibodies that inhibit heparanization of PA63 and PA63 binding to EF or LF, inhibition of PA-mediated translocation of EF or LF across a membrane or antibodies with  $K_d$  less than or equal to  $10^{-11}$  M or  $10^{-12}$  M* for all the reasons made of record.

Applicants amendment does not obviate the enablement rejection as applied to the dependent claims.

### ***Status of Claims***

Claims 22-32, 57-66, 79-86 and 97-104 are withdrawn from consideration.

Claims 1, 7-14, 17-21, 33-37, 41-46, 51, 52, 55, 67, 69 and 70 are allowable.

Claims 5, 6, 15 and 16 stand rejected.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner

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